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SUBJECT: RUSSIA HEALTH REGULATOR DISMISSED AFTER PUBLIC COMMENTS ON DRAFT PHARMA LAW

REF: MOSCOW 189

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¶1. (SBU) SUMMARY: On February 6, Prime Minister Putin dismissed Nikolai Yurgel, head of Russian pharmaceutical watchdog Roszdravnadzor, two days after Yurgel publicly criticized the government's draft "Law on the Circulation of Medicines," echoing numerous objections of the pharmaceutical industry and other stakeholders. The USG has expressed concerns about the draft relating to intellectual property rights and drug testing requirements. Yurgel also had a parochial reason to object to the bill: if passed, it would move drug and testing from Roszdravnadzor into a new agency. Despite Yurgel's firing, the intellectual property rights issue may still be addressed through an amendment which has been drafted, but not submitted to the Duma. But Yurgel has had difficult relations with Health and Social Development Minister Golikova for some time, and his criticism of the law may have been simply a convenient excuse for his dismissal. END SUMMARY.

HEALTH REGULATOR SPEAKS OUT, LOSES JOB

¶2. (U) On February 6, Prime Minister Putin dismissed Nikolai Yurgel, head of the Russian Federal Service for Surveillance in the Sphere of Health and Social Development (Roszdravnadzor), the agency responsible for supervision and regulation of the pharmaceutical industry. Yurgel has headed the agency since March 2007. His dismissal came two days after he publicly criticized the government's draft "Law on the Circulation of Medicines," now in the Duma. He commented on the draft law in an interview printed in the newspaper "Vzglyad," saying that the draft needed serious work. He also agreed with the concerns raised by the private sector and other groups and warned that the law would open the doors to corruption.

¶3. (U) The official justification for his sacking was "violation of the law on state service." Article 17 of that law prohibits government officials from publicly commenting on the activities and

decisions of state bodies and leaders. Yurgel is the first federal official fired for violating this law. In announcing the dismissal, the government press service explained that Yurgel "publicly expressed his disagreement with the position of the Ministry of Health and Social Development (MOHSD), allowing statements similar to positions of a number of experts who either didn't read the details of the text and didn't understand its novelty, or are openly lobbying somebody's interests."

OBJECTIONS TO THE DRAFT LAW ON MEDICINES

¶4. (SBU) The draft law was developed by the Ministry of Health and Social Development (MOHSD) with no involvement by Roszdravnadzor or outside trade and health experts. It was submitted to the State Duma for consideration at the end of 2009. The draft was approved by the State Duma in its first reading on January 29. (NOTE: Before the bill can become law, it must pass two more readings in the Duma, and then be approved by a vote of the upper chamber of parliament and signed by the President. END NOTE.)

¶5. (SBU) The text has come under fire from the pharmaceutical industry, health experts, patients' rights groups, and the Federal Antimonopoly Service. In December, Ambassador Beyrle explained U.S. concerns with the law to MOHSD Deputy Minister Veronika Skvortsova (reftel). Specifically, the draft law does not provide six years of data exclusivity protection as agreed to in the 2006 IPR side letter, part of the U.S.-Russia bilateral agreement for Russia's accession to the World Trade Organization. The bill also requires, if only by implication, that any new drugs undergo clinical testing in Russia in order to be registered in the country. (NOTE: The draft requires that trial results presented at registration come from facilities and medical institutions accredited by the Russian

government; the government cannot accredit medical institutions outside of Russia. END NOTE.)

¶6. (U) Diverse stakeholders met with the ruling United Russia faction in the Duma on February 4 to discuss concerns about the draft law. Their wide-ranging complaints included the fear that the law would give excessive powers to MOHSD, and that a massive proposed hike in drug registration fees would raise drug prices for consumers and government health services and threaten producers of low-cost drugs and some innovative drugs. According to health experts quoted in the media, the requirement for all drugs to be tested in Russian facilities would risk depriving Russian patients of critical medications that have already been successfully tested in other countries. In a press quote, Timofey Nizhegorodtsev, a department director in the Federal Antimonopoly Service, called the law "weak" and expressed astonishment at the idea of requiring clinical trials in Russia for drugs already approved abroad.

ROSZDRAVNADZOR VS. THE HEALTH MINISTRY

¶7. (U) Yurgel also had his own parochial reasons to object to the law, which reflect a rivalry between Roszdravnadzor and MOHSD, its parent ministry. Although Roszdravnadzor is the lead agency on drug registration and quality control, it is almost not mentioned in the text of the draft law. The law would create a new agency responsible for testing of new drugs, a function that now belongs to Roszdravnadzor.

¶8. (U) Roszdravnadzor was established in 2004 as part of a government restructuring that separated public health policymaking, supervision, and implementing functions into three separate entities. Roszdravnadzor, a supervision agency, received control over registration and quality control of drugs and medical devices, licensing of health care facilities, authorization of clinical trials, and other functions. Aleksey Makarkin, Vice-President of a Russian think-tank, the Center for Political Technologies, was quoted in the newspaper "Nezavisimaya Gazeta" saying that Minister of Health and Social Development Tatyana Golikova has worked to

gradually bring some supervision and implementing functions back under the Ministry's direct control. Two implementing agencies created in the 2004 restructuring have already been eliminated, returning most of their functions to MOHSD.

COMMENT: CONSEQUENCES OF YURGEL'S FIRING

¶9. (SBU) Despite Yurgel's dismissal, we understand from discussions with the Ministry of Economic Development that that ministry is working on amendments, either to the current Law on Medicines, or to MOHSD's new draft, to address the intellectual property provisions for compliance with the Trade Related Aspects of Intellectual Property (TRIPs) Agreement. But these amendments have not yet been submitted to the Duma. In terms of our work with Roszdravnadzor, our senior contacts at the agency have indicated to us that Yurgel's departure will not affect those activities -- specifically, a proposed project with the U.S. Food and Drug Administration aimed at implementing Good Clinical Practice in Russia. And judging from press comments on the difficult relationship between Yurgel and the Health Ministry, Yurgel's comments on the draft law may have been only a convenient excuse for his dismissal.

BEYRLE